MAY - 3 2001

510(k) Summary

Galil Medical - SeedNet™ with STPS System

510(k) Number:
K010991

Company Name:
Galil Medical Ltd.

Contact Person:
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Director of IP & Regulatory Affairs
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Trade Proprietary Name:
SeedNet™ with SeedNet Training and Planning Software.

Classification Name:
CRYOSURGICAL UNIT

Classification:
GEH

Predicate Devices:
1. SeedNet™
2. CRYO-HIT™
3. Endocare Inc.'s Cryocare Cryosurgical System with CryoGuide™

K010991

Indication for Use:

The SeedNet™ System with STPS is intended for cryogenic destruction of tissue during surgical procedures.
The system is specifically indicated for Urology (ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia "BPH").

Technological Characteristics:

The Galil Medical's SeedNet™ System with the SeedNet Training and Planning Software ("STPS") is a modification of Galil Medical LTD's cleared SeedNet™ System (K003065). The SeedNet™ System with the STPS is the exact same device as the SeedNet™ except for the following modifications:

1. Removal of the internal Gas Cylinders
2. Integration of the multiprobe distribution panel into the device's framers
3. Inclusion of the Training and Planning Software which creates and displays a computer simulation of cryoablation of the prostate prior to the activation of freezing/thawing cycles
4. Substitution of one brand of warmer for another brand of warmer in the device's transurethral warmer system and the use of an IV stand with the warmer
5. Provision of the SeedNet's disposable sensors, probe, warmer tubes, and warmer catheter as a disposable kit
6. Change in the overpressure threshold to which the device complies in order to be consistent with the test requirement set forth in the applicable FDA recognized consensus standard.

The SeedNet™ System with the STPS consists of the same components as the former SeedNet™ system (K003065) excluding the use of internal gas cylinders. Use of internal cylinders was one optional way of using the system, while the other option, use of external gas cylinders as a source for energy, still exists in the SeedNet™ System with the STPS.

The removal of the internal gas cylinders enables the straightforward integration of the Multiprobe Distribution Panel (MDP), which was previously an accessory to the cleared Cryo-Hit™ (K993965) and the SeedNet™ (K003065) systems, into the frame of the SeedNet with STPS.

Galil conducted validation testing of the SeedNet with the MediTemp II warmer. The conclusions drawn from that validation testing were as follows: (a) the pictures included in the report clearly show a freeze free zone around the TUW's catheter; (b) the Mallinckrodt WarmFlo and Gaymar's Medi-Temp II both warmed the water entering the catheter to 42 to 43 °C after five minutes of warming; (c) the temperature of the water exiting the TUW catheter during the freeze cycle is approximately 1°C lower with Gaymar's Medi-Temp II than with Mallinckrodt's WarmFlo; and (d) both products maintain the temperature of the water in the catheter above 37°C, *i.e.*, body temperature. Thus, the validation test results showed that the modification does not raise new safety or effectiveness questions.

The STPS and the CryoGuide™ are both software products for use as physician training and planning tools for probe placement during cryoablation of the prostate. The use of the SeedNet Training and Planning Software ("STPS"), which creates and displays a computer simulation of cryoablation of the prostate is substantially equivalent to EndoCare, Inc.'s CryoCare Surgical System with CryoGuide™ (K002615).

The overpressure to which the SeedNet with STPS was tested was changed from four times to twice its maximum working pressure in order to be consistent with the overpressure test requirement set forth in ASTM F 882-96. Galil included a signed certification in the 510(k) notice that the SeedNet with STPS met that test requirement.

Substantial Equivalence:

The SeedNet with STPS has the same intended use and indications, and very similar principles of operation, and technological characteristics as the cleared SeedNet, Cryo-Hit, and/or CryoCare with CryoGuide. The minor technological differences between the SeedNet with STPS and its predicate devices, namely the integration of the Multiprobe Distribution Panel in the SeedNet with STPS, the removal of the internal gas cylinders, and the use of a different brand of transurethral warmer, do not raise any new questions of safety or effectiveness. Thus, the SeedNet™ System with the STPS is substantially equivalent to a combination of the SeedNet™ system (K003065) and Endocare Inc.'s CryoCare Cryosurgical System with CryoGuide™ (K002615).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Galil Medical, Ltd.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K010991
Trade/Device Name: SeedNet™ With SeedNet Training and Planning Software
Regulation Number: 878.4350
Regulatory Class: II
Product Code: GEH
Dated: April 2, 2001
Received: April 3, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K010991

Device Name: SeedNet™ System with SeedNet Training and Planning Software

Indications for Use:

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K010991

Prescription Use ✓